UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/635,974	08/09/2000	Thomas Teufel	381-86	5643

7590 11/18/2003

Deborah A. Somerville
Kenyon & Kenyon
One Broadway
New York, NY 10004

EXAMINER	
HOLLERAN, ANNE L	

ART UNIT	PAPER NUMBER
1642	16

DATE MAILED: 11/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n N .	Applicant(s)	
	09/635,974	TEUFEL, THOMAS	
	Examiner	Art Unit	
	Anne Holleran	1642	

-- The MAILING DATE f this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 April 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 8-44* is/are pending in the application.

4a) Of the above claim(s) *8-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachm nt(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. The amendment filed April 29, 2003 is acknowledged. Claims 6 and 7 were canceled. (However, for clarification of the record it is noted that there appears to be an error in the "Version to Show Changes Made", because a "claim 6" is set forth with changes). New claim 44 (misnumbered as claim "8") was added.

Claims 1-5 and 8-44 are pending. Claims 8-44, drawn to non-elected inventions, are withdrawn from consideration. (New claim 44 does not read on the elected species.) Claims 1-5 are examined on the merits.

Claim Rejections Withdrawn:

2. The rejection of claims 1-7 under 35 U.S.C. 112, first paragraph, for lack of enablement commensurate with the scope of the claimed invention, is withdrawn upon further consideration.

3. The rejection of claims 1-5 under 35 U.S.C. 103(a) as being unpatentable over the prior art is withdrawn upon further consideration.

New Grounds of Rejection:

4. Claims 1-3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wels (U.S. Patent 6,129,915; issued 10/2000; effective filing 02/1997) or Mendelsohn (U.S. Patent 4,943,533; issued 07/1990; effective filing 03/1984; cited in IDS) in view of Varani (Varani, J. et

al., Pathobiology, 66: 253-259, 1998; cited in previous Office action) and further in view of McMahon (U.S. Patent 6,004,967; issued 12/1999; effective filing 06/1997; cited in IDS).

The claimed inventions are drawn to methods of treating a mammal with psoriasis comprising systemically administering and EGFR/Her1 antagonist that is an anti-EGFR antibody. The antibody may be a monoclonal antibody or a fragment that comprises the hypervariable region of the monoclonal antibody. The monoclonal antibody may inhibit EGFR phosphorylation.

Wels teaches a single chain polypeptide that comprises the heavy and light chains of the 14E1 antibody, an antibody that inhibits EGFR activation (col. 9, line 60 – col. 10, line 41). Wels teaches and claims a method for blocking cell proliferation comprising administering the single chain polypeptide (see claim 6 and col. 3, lines 47-61). Mendelsohn teaches several monoclonal antibodies that bind to the EGFR, and some that block ligand activation of EGFR (inhibits EGFR phosphorylation), and teaches methods where the antibody is administered systemically to mice (col.8, line 44 – col. 9, line 25).

Varani teaches that monoclonal antibody 225 partially ameliorated the abnormal histological features of psoriatic tissue maintained in vitro.

McMahon teaches methods for systemic administration of pharmaceutical preparation containing a quinazoline compound that inhibits the EGFR tyrosine kinase activity (see col. 1, line 66 – col. 2, line 20; col. 17, lines 35 – 48; claim 6).

Either Wels or Mendelsohn teaches methods comprising the systemic administration of antibodies to mammals for the purpose of inhibition of cell proliferation. Neither Wels nor Mendelsohn teaches methods with the specific purpose of treating a mammal with psoriasis.

However, Varani teaches that targeting the EGFR receptor with the monoclonal antibody, 225, reduces psoriatic histological features. Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used the methods of either Wels or Mendelsohn for the treatment of a mammal having psoriasis. McMahahon is cited to demonstrate that even in non-antibody arts, systemic administration of a therapeutic agent, intended to treat psoriasis by inhibiting EGFR activity, is known and envisioned. Therefore, applicant's arguments that systemic administration was not taught by the prior art is not found persuasive.

5. Claims 1, 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wels (U.S. Patent 6,129,915; issued 10/2000; effective filing 02/1997) or Mendelsohn (U.S. Patent 4,943,533; issued 07/1990; effective filing 03/1984; cited in IDS) in view of Varani (Varani, J. et al., Pathobiology, 66: 253-259, 1998; cited in previous Office action) and further in view of Goldstein (WO 96/40210; published 12/1996; cited in a previous Office action).

The claimed inventions read on methods where the anti-EGFR antibody is chimerized or humanized.

Neither Wels nor Mendelsohn teach chimeric or humanized versions of antibodies that bind to the EGFR, and the combination with Varani fails to teach methods comprising the use of chimeric or humanized anti-EGFR antibodies. However, methods for making chimeric or humanized versions of monoclonal antibodies are known in the art as evidenced by the teachings of Goldstein. Furthermore, Goldstein teaches the motivation for using a chimeric or humanized anti-EGFR antibody, because Goldstein teaches that the use of purely murine antibodies can

sometimes result in a human anti-mouse antibody response (HAMA response), and that the HAMA response is reduced by making a chimeric or humanized version of an antibody (see page 3, lines 5-20). Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used the chimeric or humanized versions of anti-EGFR antibodies of Goldstein in the methods of Wels or Mendelsohn for the treatment of psoriasis.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran
Patent Examiner
November 17, 2003

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600